DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 01N–0576]

Medical Devices; Reclassification of the Cutaneous Carbon Dioxide and the Cutaneous Oxygen Monitor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the cutaneous carbon dioxide ($PcCO_2$) monitor from class II (performance standards) into class II (special controls). FDA is also reclassifying the cutaneous oxygen (PcO_2) monitor for an infant patient who is not under gas anesthesia from class II (performance standards) into class II (special controls) and is reclassifying the cutaneous oxygen (PcO_2) monitor for all other uses from class III (premarket approval) into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA" that will serve as the special control for the devices. These reclassifications are taken on the agency's own initiative based on new information. These actions are being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: William A. Noe, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 174.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et. seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance. The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

It is the agency's position that it is not necessary to obtain a new classification recommendation from a panel that had recommended classification into class II prior to the SMDA. If a panel recommended that a device be classified into class II under the 1976 definition of class II, which included only performance standards as a class II control, clearly the Panel's

recommendation for class II status would not change if controls, in addition to performance standards, could be added.

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon "new information." The reclassification can be initiated by FDA or by the petition of an interested person. The term "new information,"

as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in "medical science." (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the "new information" on which any reclassification is based is required to consist of "valid scientific evidence," as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985). FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the act (21 U.S.C. 360j(c).)

In accordance with section 513(e) of the act and 21 CFR 860.130(b)(1), based on new information with respect to the device, FDA, on its own initiative, is reclassifying the $PcCO_2$ monitor from class II (performance standards) into class II (special controls). FDA is also reclassifying the PcO_2 monitor for an infant patient who is not under gas anesthesia from class II (performance standards) into class II (special controls) and the PcO_2 monitor for all other uses from class III (premarket approval) into class II (special controls).

FDAMA added a new section 510(m) to the act. Section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k), if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to assure the safety and effectiveness of the $PcCO_2$ monitor and the PcO_2 monitor.

II. Regulatory History of the Device

In the **Federal Register** of February 12, 2002 (67 FR 6444), FDA published a proposed rule reclassifying the $PcCO_2$ monitor from class II (performance standards) into class II (special controls), the PcO_2 monitor for an infant patient who is not under gas anesthesia from class II (performance standards) into class II (special controls), and the PcO_2 monitor for all other uses from class III (premarket approval) into class II (special controls), on the agency's own initiative based on new information.

FDA also identified the document "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA" as the special control applicable to these devices.

Interested persons were invited to comment on the proposed rule by April 15, 2002, and on the draft special control guidance document by May 13, 2002. FDA received no comments on the proposed rule. FDA received two comments on the draft guidance document and they are discussed in the notice of availability for the guidance published elsewhere in this issue of the **Federal Register**.

Based on a review of the available information, FDA concludes that the guidance document "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA," in conjunction with general controls, provides reasonable assurance of the safety and effectiveness of these devices. Following the effective date of this final rule, any firm submitting a 510(k) premarket notification for the $PcCO_2$ monitor or the PcO_2 monitor will need to address the issues covered in the special control guidance. However,

the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document.

III. Summary of Final Rule

FDA is adopting the assessment of the risks to public health stated in the proposed rule published on February 12, 2002. Furthermore, FDA is issuing a final rule that revises §§ 868.2480 and 868.2500, thereby reclassifying the generic type of device, $PcCO_2$ monitor, from class II (performance standards) into class II (special controls) and the generic type of device, PcO_2 monitor, for an infant patient who is not under gas anesthesia from class II (performance standards) into class II (special controls), and for all other uses, from class III (premarket approval) into class II (special controls). The special control capable of providing reasonable assurance of safety and effectiveness for these devices is a guidance document entitled "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA." This guidance document describes a means by which $PcCO_2$ and PcO_2 monitor devices may comply with the requirement of special controls for class II devices. Following the effective date of this final rule, any firm submitting a premarket notification (510(k)) for a $PcCO_2$ monitor or PcO_2 monitor will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

For the convenience of the reader, FDA is adding new § 868.1(e) to inform the reader where to find guidance documents referenced in 21 CFR part 868.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that these classification actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et. seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the cutaneous oxygen monitor from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act. Furthermore, this rule may permit small potential competitors to enter the marketplace by lowering their costs.

Compliance with special controls for the cutaneous oxygen monitor and the cutaneous carbon dioxide monitor will not impose significant new costs on affected manufacturers because most of these devices already comply with the special controls. Based upon its review of the information submitted in premarket notifications for these devices, FDA believes that manufacturers presently marketing these devices are in conformance with the guidance document. The guidance document assures that, in the future, these generic types of devices will be at least as safe and effective as the presently marketed devices. These devices are already subject to premarket notification and labeling requirements. The guidance document advises manufacturers on appropriate means of complying with these requirements.

The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of $100

million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

The final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA) is not required.

The information collections addressed in the special control guidance document identified by this rule have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB in accordance with the PRA under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 868.1 is amended by adding paragraph (e) to read as follows:

§ 868.1 Scope.

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(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/cdrh/guidance.html.

3. Section 868.2480 is amended by revising paragraph (b) to read as follows:

§ 868.2480 Cutaneous carbon dioxide ($PcCO_2$) monitor.

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(b) *Classification*. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA." See § 868.1(e) for the availability of this guidance document.

4. Section 868.2500 and the section heading is revised to read as follows:

§ 868.2500 Cutaneous oxygen (PcO_2) monitor.

(a) *Identification*. A cutaneous oxygen (PcO_2) monitor is a noninvasive, heated sensor (e.g., a Clark-type polargraphic electrode) placed on the patient's skin that is intended to monitor relative changes in the cutaneous oxygen tension.

(b) *Classification*. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA." See § 868.1(e) for the availability of this guidance document.

Dated: December 2, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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